LITE DEPALMA GREENBERG, LLC
Michael E. Patunas
Mayra V. Tarantino
570 Broad Street, Suite 1201
Newark, NJ 07102
Telephone: (973) 623-3000
Facsimile: (973) 623-0858
mpatunas@litedepalma.com
mtarantino@litedepalma.com

Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

VIVUS, INC.,	:	Civil Action No.: 15-2693(SRC)(CLW)
Plaintiff,	:	**DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**
v.	:	
TEVA PHARMACEUTICALS USA, INC.	:	
Defendant.	:	

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") by and through the undersigned attorneys, submits its answer, affirmative defenses, and counterclaims to the Complaint for patent infringement of Plaintiff VIVUS, Inc. ("VIVUS"). Teva USA denies all allegations in VIVUS's Complaint except those admitted specifically below. This pleading is based upon Teva USA's knowledge as to its own activities, and upon information and belief as to the activities of others.

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Teva's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of VIVUS' QSYMIA® drug products prior to the expiration of United States Patent Nos. 7,056,890 (the "'890 patent"), 7,553,818 (the "'818 patent"), 7,659,256 (the "'256 patent"), 7,674,776 (the "'776 patent"), 8,580,298 (the "'298

patent"), 8,580,299 (the "'299 patent"), 8,895,057 (the "'057 patent"), and 8,895,058 (the "'058 patent") owned by VIVUS (collectively, "the patents-in-suit").

ANSWER: Teva USA admits that the Complaint purports to bring an action for patent infringement of the patents listed in this paragraph arising from Teva USA's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of VIVUS' QSYMIA® drug products. Teva USA lacks knowledge or information sufficient to form a belief as to the truth or falsity of whether VIVUS owns the patents-in-suit and, therefore, denies those allegations. Teva USA denies that VIVUS is entitled to any relief in this action. Teva USA denies the remaining allegations of this paragraph.

The Parties

2. Plaintiff VIVUS is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 351 E. Evelyn Avenue, Mountain View, California 94041.

ANSWER: On information and belief, Teva USA admits that VIVUS is a corporation organized and existing under the laws of the State of Delaware. Teva USA lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies those allegations.

3. On information and belief, defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

ANSWER: Teva USA admits the allegations in this paragraph.

4. On information and belief, defendant Teva Pharmaceutical Industries Ltd. is an Israeli corporation having a principal place of business at 5 Basel Street, Petah Tikva 49131, Israel.

ANSWER: Teva USA denies that Teva Pharmaceutical Industries Ltd. is a "defendant" in this action. Pursuant to the Stipulation and Order of Dismissal dated June 5,

2015, the action against Teva Pharmaceutical Industries Ltd. has been dismissed. *See* ECF No. 13. Accordingly, no response to allegations regarding Teva Pharmaceutical Industries Ltd. is required from Teva USA.

5. On information and belief, defendant Teva Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of defendant Teva Pharmaceutical Industries Ltd.

ANSWER: Teva USA admits that it is an indirect wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. Teva USA denies the remaining allegations in this paragraph.

6. On information and belief, defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. manufacture and/or distribute generic drugs for sale and use throughout the United States, including in this Judicial District. On information and belief, defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. also prepare and/or aid in the preparation and submission of ANDAs to the FDA.

ANSWER: Teva USA denies that Teva Pharmaceutical Industries Ltd. is a "defendant" in this action. Pursuant to the Stipulation and Order of Dismissal dated June 5, 2015, the action against Teva Pharmaceutical Industries Ltd. has been dismissed. *See* ECF No. 13. Accordingly, no response to allegations regarding Teva Pharmaceutical Industries Ltd. is required from Teva USA. Teva USA admits that it manufactures generic drugs for sale and use in the United States, including for sale and use in this Judicial District, and that it has prepared and submitted ANDAs to the FDA. Teva USA denies the remaining allegations in this paragraph.

7. On information and belief, the acts of Teva Pharmaceuticals USA, Inc. complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of, Teva Pharmaceutical Industries Ltd.

ANSWER: Pursuant to the Stipulation and Order of Dismissal dated June 5, 2015, the action against Teva Pharmaceutical Industries Ltd. has been dismissed. *See* ECF No. 13. Accordingly, no response to allegations regarding Teva Pharmaceutical Industries Ltd. is required from Teva USA.

Jurisdiction and Venue

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA admits the allegations in this paragraph.

9. This Court has personal jurisdiction over Teva Pharmaceuticals USA, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Teva Pharmaceuticals USA, Inc. is registered to do business in the State of New Jersey under entity ID No. 0100250184. In addition, on information and belief, Teva Pharmaceuticals USA, Inc. has appointed a registered agent for service of process in New Jersey (Corporate Creations Network Inc., 811 Church Road #105, Cherry Hill, NJ 08002).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA admits that it is registered to do business in the State of New Jersey under entity ID No. 0100250184. Teva USA further admits that it has appointed a registered agent for service of process in New Jersey (Corporate Creations Network Inc., 811 Church Road #105, Cherry Hill, NJ 08002). Teva USA denies that it is subject to personal jurisdiction in this district. For purposes of this action only, however, and solely to conserve the resources of the parties and the Court, Teva USA does not contest personal jurisdiction in this judicial district. Teva USA denies the remaining allegations of this paragraph.

10. On information and belief, Teva Pharmaceuticals USA, Inc. holds licenses in the State of New Jersey as a "wholesaler" and "manufacturer and wholesaler" of drugs, with License Nos. 5003436 and 5000583, respectively. On information and belief, Teva Pharmaceuticals USA, Inc. employs people throughout the State of New Jersey, including at least the following two locations: 8 Gloria Ln, Fairfield, NJ 07004 and 400 Chestnut Ridge Rd, Woodcliff Lake, NJ 07677. On information and belief, Teva Pharmaceuticals USA, Inc. conducts business in this District and purposefully avails itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Also, on information and belief, Teva Pharmaceuticals USA, Inc. has customers in the State of New Jersey.

ANSWER: This paragraph contains conclusions of law for which no response is

required. To the extent a response is required, Teva USA admits that it holds licenses in the State of New Jersey as a "wholesaler" and "manufacturer and wholesaler" of drugs, with License Nos. 5003436 and 5000583, respectively. Teva USA further admits that it employs people in the State of New Jersey at these two locations: 8 Gloria Ln, Fairfield, NJ 07004 and 400 Chestnut Ridge Rd, Woodcliff Lake, NJ 07677. Teva USA further admits that it has customers in the State of New Jersey. Teva USA denies that it is subject to personal jurisdiction in this district. For purposes of this action only, however, and solely to conserve the resources of the parties and the Court, Teva USA does not contest personal jurisdiction in this judicial district. Teva USA denies the remaining allegations of this paragraph.

11. On information and belief, Teva Pharmaceuticals USA, Inc. has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following cases: *Amarin Pharma, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, No. 14-3558, *Boehringer Ingelheim Pharma GmbH & Co. KG, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-7811, *Helsinn Healthcare S.A., et al., v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-6341, *Novo Nordisk Inc., et al., v. Teva Pharmaceuticals USA, Inc.*, No. 14-4248, *Otsuka Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-5878, *United Therapeutics Corp. v. Teva Pharmaceuticals USA, Inc.*, No. 14-5498. Further, on information and belief, Teva Pharmaceuticals USA, Inc. has purposefully availed itself of the benefits of this forum by filing counterclaims in each of those actions. Additionally, on information and belief, Teva Pharmaceuticals USA, Inc. has availed itself of this forum by bringing civil actions for patent infringement in this forum in at least the following cases: *Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories, Ltd., et al.*, No. 14-5672, *Teva Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, No. 15-472.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA admits that it has been sued for patent infringement in this District and did not contest personal jurisdiction in the following cases: *Amarin Pharma, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, No. 14-3558, *Boehringer Ingelheim Pharma GmbH & Co. KG, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-7811, *Helsinn Healthcare S.A., et al., v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-6341, *Novo Nordisk Inc., et al., v. Teva Pharmaceuticals USA, Inc.*, No. 14-4248, *Otsuka*

Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals USA, Inc., et al., No. 14-5878, *United Therapeutics Corp. v. Teva Pharmaceuticals USA, Inc.*, No. 14-5498. Teva USA further admits that it filed counterclaims in each of those actions. Teva USA further admits that it has brought civil actions for patent infringement in this District in the following cases: *Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories, Ltd., et al.*, No. 14-5672, *Teva Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, No. 15-472. Teva USA denies that it is subject to personal jurisdiction in this district. For purposes of this action only, however, and solely to conserve the resources of the parties and the Court, Teva USA does not contest personal jurisdiction in this judicial district. Teva USA denies the remaining allegations of this paragraph.

12. This Court has personal jurisdiction over Teva Pharmaceutical Industries Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Teva Pharmaceutical Industries Ltd. conducts business in this District, and purposefully avails itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Also, on information and belief, Teva Pharmaceutical Industries Ltd. has customers in the State of New Jersey.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA denies that this Court has personal jurisdiction over Teva Pharmaceutical Industries Ltd. in this matter. Pursuant to the Stipulation and Order of Dismissal dated June 5, 2015, the action against Teva Pharmaceutical Industries Ltd. has been dismissed. *See* ECF No. 13. Accordingly, no response to allegations regarding Teva Pharmaceutical Industries Ltd. is required from Teva USA.

13. On information and belief, Teva Pharmaceutical Industries Ltd. has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following case: *Boehringer Ingelheim Pharma GmBH & Co. KG, et al. v. Teva Pharmaceuticals USA, Inc., et al*, No. 14-7811. Further, on information and belief, Teva Pharmaceutical Industries Ltd. has purposefully availed itself of the benefits of this forum by filing counterclaims in that action. Additionally, on information and belief, Teva Pharmaceutical Industries Ltd. has availed itself of the benefits of this forum by bringing civil actions for patent infringement in this forum. *See, e.g., Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories, Ltd., et al.*, No. 14-5672, *Teva Pharmaceuticals USA, Inc., et al. v. Synthon*

Pharmaceuticals, Inc., et al., No. 15-472.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA denies that this Court has personal jurisdiction over Teva Pharmaceutical Industries Ltd. in this matter. Pursuant to the Stipulation and Order of Dismissal dated June 5, 2015, the action against Teva Pharmaceutical Industries Ltd. has been dismissed. *See* ECF No. 13. Accordingly, no response to allegations regarding Teva Pharmaceutical Industries Ltd. is required from Teva USA.

14. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA does not contest that venue is proper in this Court for the purposes of this action only. Teva USA denies the remaining allegations in this paragraph.

The Patents-In-Suit

15. On June 6, 2006, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '890 patent, entitled "Combination therapy for effecting weight loss and treating obesity" to VIVUS as assignee of the inventor Thomas Najarian. A copy of the '890 patent is attached hereto as Exhibit A.

ANSWER: Teva USA admits that on June 6, 2006, the United States Patent and Trademark Office ("USPTO") issued the '890 patent, entitled "Combination therapy for effecting weight loss and treating obesity," a purported copy of which was attached as Exhibit A to the Complaint. Teva USA further admits that, on the face of the '890 patent, Thomas Najarian is listed as the inventor and that VIVUS, Inc. is listed as the assignee. Teva USA denies that the '890 patent was duly and lawfully issued. Teva USA denies the remaining allegations of this paragraph.

16. On June 30, 2009, the USPTO duly and lawfully issued the '818 patent, entitled "Combination therapy for effecting weight loss and treating obesity" to VIVUS as assignee of

the inventor Thomas Najarian. A copy of the '818 patent is attached hereto as Exhibit B.

ANSWER: Teva USA admits that on June 30, 2009, the USPTO issued the '818 patent, entitled "Combination therapy for effecting weight loss and treating obesity," a purported copy of which is attached as Exhibit B to the Complaint. Teva USA further admits that, on the face of the '818 patent, Thomas Najarian is listed as the inventor and that VIVUS, Inc. is listed as the assignee. Teva USA denies that the '818 patent was duly and lawfully issued. Teva USA denies the remaining allegations of this paragraph.

17. On February 9, 2010, the USPTO duly and lawfully issued the '256 patent, entitled "Combination therapy for effecting weight loss and treating obesity" to VIVUS as assignee of the inventor Thomas Najarian. A copy of the '256 patent is attached hereto as Exhibit C.

ANSWER: Teva USA admits that on February 9, 2010, the USPTO issued the '256 patent, entitled "Combination therapy for effecting weight loss and treating obesity," a purported copy of which is attached as Exhibit C to the Complaint. Teva USA further admits that, on the face of the '256 patent, Thomas Najarian is listed as the inventor and that VIVUS, Inc. is listed as the assignee. Teva USA denies that the '256 patent was duly and lawfully issued. Teva USA denies the remaining allegations of this paragraph.

18. On March 9, 2010, the USPTO duly and lawfully issued the '776 patent, entitled "Combination therapy for effecting weight loss and treating obesity" to VIVUS as assignee of the inventor Thomas Najarian. A copy of the '776 patent is attached hereto as Exhibit D.

ANSWER: Teva USA admits that on March 9, 2010, the USPTO issued the '776 patent, entitled "Combination therapy for effecting weight loss and treating obesity," a purported copy of which is attached as Exhibit D to the Complaint. Teva USA further admits that, on the face of the '776 patent, Thomas Najarian is listed as the inventor and that VIVUS, Inc. is listed as the assignee. Teva USA denies that the '776 patent was duly and lawfully issued. Teva USA denies the remaining allegations of this paragraph.

19. On November 12, 2013, the USPTO duly and lawfully issued the '298 patent, entitled "Low dose topiramate/phentermine composition and methods of use thereof" to VIVUS as assignee of the inventors Thomas Najarian, Peter Y. Tam and Leland F. Wilson. A copy of the '298 patent is attached hereto as Exhibit E.

ANSWER: Teva USA admits that on November 12, 2013, the USPTO issued the '298 patent, entitled "Low dose topiramate/phentermine composition and methods of use thereof," a purported copy of which is attached as Exhibit E to the Complaint. Teva USA further admits that, on the face of the '298 patent, Thomas Najarian, Peter Y. Tam, and Leland F. Wilson are listed as the inventors and that VIVUS, Inc. is listed as the assignee. Teva USA denies that the '298 patent was duly and lawfully issued. Teva USA denies the remaining allegations of this paragraph.

20. On November 12, 2013, the USPTO duly and lawfully issued the '299 patent, entitled "Escalating dosing regimen for effecting weight loss and treating obesity" to VIVUS as assignee of the inventors Thomas Najarian, Peter Y. Tam and Leland F. Wilson. A copy of the '299 patent is attached hereto as Exhibit F.

ANSWER: Teva USA admits that on November 12, 2013, the USPTO issued the '299 patent, entitled "Escalating dosing regimen for effecting weight loss and treating obesity," a purported copy of which is attached as Exhibit F to the Complaint. Teva USA further admits that, on the face of the '299 patent, Thomas Najarian, Peter Y. Tam, and Leland F. Wilson are listed as the inventors and that VIVUS, Inc. is listed as the assignee. Teva USA denies that the '299 patent was duly and lawfully issued. Teva USA denies the remaining allegations of this paragraph.

21. On November 25, 2014, the USPTO duly and lawfully issued the '057 patent, entitled "Escalating dosing regimen for effecting weight loss and treating obesity" to VIVUS as assignee of the inventors Thomas Najarian, Peter Y. Tam, and Leland F. Wilson. A copy of the '057 patent is attached hereto as Exhibit G.

ANSWER: Teva USA admits that on November 25, 2014, the USPTO issued the '057 patent, entitled "Escalating dosing regimen for effecting weight loss and treating obesity," a

purported copy of which is attached as Exhibit G to the Complaint. Teva USA further admits that, on the face of the '057 patent, Thomas Najarian, Peter Y. Tam, and Leland F. Wilson are listed as the inventors and that VIVUS, Inc. is listed as the assignee. Teva USA denies that the '057 patent was duly and lawfully issued. Teva USA denies the remaining allegations of this paragraph.

22. On November 25, 2014, the USPTO duly and lawfully issued the '058 patent, entitled "Low dose topiramate/phentermine composition and methods of use thereof" to VIVUS as assignee of the inventors Thomas Najarian, Peter Y. Tam, and Leland F. Wilson. A copy of the '058 patent is attached hereto as Exhibit H.

ANSWER: Teva USA admits that on November 25, 2014, the USPTO issued the '058 patent, entitled "Low dose topiramate/phentermine composition and methods of use thereof," a purported copy of which is attached as Exhibit H to the Complaint. Teva USA further admits that, on the face of the '058 patent, Thomas Najarian, Peter Y. Tam, and Leland F. Wilson are listed as the inventors and that VIVUS, Inc. is listed as the assignee. Teva USA denies that the '058 patent was duly and lawfully issued. Teva USA denies the remaining allegations of this paragraph.

The QSYMIA® Drug Products

23. VIVUS holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for phentermine and topiramate extended-release capsules (NDA No. 022580), which it sells under the trade name QSYMIA®. The claims of the patents-in-suit cover, *inter alia,* pharmaceutical compositions containing combinations of phentermine and topiramate, and methods of use and administration of combinations of phentermine and topiramate. VIVUS owns the patents-in-suit.

ANSWER: Teva USA admits that the FDA website Drugs@FDA lists VIVUS, Inc. as the holder of New Drug Application ("NDA") No. 022580 for Qsymia® (phentermine and topiramate extended-release) capsules. Teva USA lacks knowledge or information sufficient to form a belief as to the truth or falsity of whether VIVUS owns the patents-in-suit and, therefore, denies those allegations. The remaining allegations of this paragraph contain conclusions of law

for which no response is required. To the extent a response is required, Teva USA denies the remaining allegations of this paragraph.

24. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to QSYMIA®.

ANSWER: Teva USA admits that the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), lists the patents-in-suit with respect to Qsymia®. The remaining allegations of this paragraph contain conclusions of law for which no response is required. To the extent a response is required, Teva USA admits the remaining allegations of this paragraph.

Acts Giving Rise to This Suit

25. Pursuant to Section 505 of the FFDCA, Teva filed ANDA No. 208175 ("Teva's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 15/92 mg, 11.25/69 mg, 7.5/46 mg, and 3.75/23 mg capsules containing as the active pharmaceutical ingredients, phentermine and topiramate extended-release ("Teva's Proposed Product"), before the patents-in-suit expire.

ANSWER: Teva USA admits that pursuant to Section 505 of the FFDCA, Teva filed ANDA No. 208175 ("Teva's ANDA") seeking approval to engage in the commercial use, manufacture, or sale of 15/92 mg, 11.25/69 mg, 7.5/46 mg, and 3.75/23 mg capsules containing as the active pharmaceutical ingredients, phentermine and topiramate extended-release ("Teva USA's ANDA Products"), before the patents-in-suit expire.

26. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Teva has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Teva's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Teva's ANDA.

ANSWER: Admitted.

27. No earlier than March 4, 2015, Teva sent written notice of its Paragraph IV Certification to VIVUS ("Teva's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Teva's Notice Letter alleged that the claims of the patents-in-suit are invalid, unenforceable, and/or will

not be infringed by the activities described in Teva's ANDA. Teva's Notice Letter also informed VIVUS that Teva seeks approval to market Teva's Proposed Product before the patents-in-suit expire.

ANSWER: Teva USA admits that on March 4, 2015, it sent written notice of its Paragraph IV Certification to VIVUS ("Teva USA's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Teva USA further admits that the Notice Letter alleged that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Teva USA's ANDA. Teva USA further admits that the Notice Letter informed VIVUS that Teva USA seeks approval to market Teva USA's Proposed Products before the patents-in-suit expire. Teva USA denies the remaining allegations of this paragraph.

Count I: Infringement of the '890 Patent

28. Plaintiff repeats and realleges the allegations of paragraphs 1-27 as though fully set forth herein.

ANSWER: Teva USA repeats and realleges its answers to the allegations of paragraphs 1-27 as though fully set forth herein.

29. Teva's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '890 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva USA admits that the submission of its ANDA vests this Court with subject matter jurisdiction over this action. Except as expressly admitted, Teva USA denies the allegations of this Paragraph.

30. There is a justiciable controversy between the parties hereto as to the infringement of the '890 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA admits the allegations in this paragraph.

31. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe the '890 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States.

ANSWER: Denied.

32. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of the '890 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '890 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

33. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe the '890 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes the '890 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

ANSWER: Denied.

34. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '890 patent is not enjoined.

ANSWER: Denied.

35. VIVUS does not have an adequate remedy at law.

ANSWER: Denied.

36. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count II: Infringement of the '818 Patent

37. Plaintiff repeats and realleges the allegations of paragraphs 1-36 as though fully set forth herein.

ANSWER: Teva USA repeats and realleges its answers to the allegations of paragraphs 1-36 as though fully set forth herein.

38. Teva's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '818 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva USA admits that the submission of its ANDA vests this Court with subject matter jurisdiction over this action. Except as expressly admitted, Teva USA denies the allegations of this Paragraph.

39. There is a justiciable controversy between the parties hereto as to the infringement of the '818 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA admits the allegations in this paragraph.

40. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe the '818 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States.

ANSWER: Denied.

41. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of the '818 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '818 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

42. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe the '818 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes the '818 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

ANSWER: Denied.

43. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '818 patent is not enjoined.

ANSWER: Denied.

44. VIVUS does not have an adequate remedy at law.

ANSWER: Denied.

45. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count III: Infringement of the '256 Patent

46. Plaintiff repeats and realleges the allegations of paragraphs 1-45 as though fully set forth herein.

ANSWER: Teva USA repeats and realleges its answers to the allegations of paragraphs 1-45 as though fully set forth herein.

47. Teva's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '256 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva USA admits that the submission of its ANDA vests this Court with subject matter jurisdiction over this action. Except as expressly admitted, Teva USA denies the allegations of this Paragraph.

48. There is a justiciable controversy between the parties hereto as to the infringement of the '256 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA admits the allegations in this paragraph.

49. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe the '256 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States.

ANSWER: Denied.

50. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will

induce infringement of the ’256 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Teva’s Proposed Product in the United States. On information and belief, upon FDA approval of Teva’s ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the ’256 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

51. Unless enjoined by this Court, upon FDA approval of Teva’s ANDA, Teva will contributorily infringe the ’256 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva’s Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva’s Proposed Product is especially adapted for a use that infringes the ’256 patent and that there is no substantial non-infringing use for Teva’s Proposed Product.

ANSWER: Denied.

52. VIVUS will be substantially and irreparably damaged and harmed if Teva’s infringement of the ’256 patent is not enjoined.

ANSWER: Denied.

53. VIVUS does not have an adequate remedy at law.

ANSWER: Denied.

54. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count IV: Infringement of the ’776 Patent

55. Plaintiff repeats and realleges the allegations of paragraphs 1-54 as though fully set forth herein.

ANSWER: Teva USA repeats and realleges its answers to the allegations of paragraphs 1-54 as though fully set forth herein.

56. Teva’s submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the ’776 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva USA admits that the submission of its ANDA vests this Court with

subject matter jurisdiction over this action. Except as expressly admitted, Teva USA denies the allegations of this Paragraph.

57. There is a justiciable controversy between the parties hereto as to the infringement of the '776 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA admits the allegations in this paragraph.

58. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe the '776 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States.

ANSWER: Denied.

59. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of the '776 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '776 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

60. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe the '776 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes the '776 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

ANSWER: Denied.

61. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '776 patent is not enjoined.

ANSWER: Denied.

62. VIVUS does not have an adequate remedy at law.

ANSWER: Denied.

63. This case is an exceptional one, and VIVUS is entitled to an award of its

reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count V: Infringement of the '298 Patent

64. Plaintiff repeats and realleges the allegations of paragraphs 1-63 as though fully set forth herein.

ANSWER: Teva USA repeats and realleges its answers to the allegations of paragraphs 1-63 as though fully set forth herein.

65. Teva's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '298 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva USA admits that the submission of its ANDA vests this Court with subject matter jurisdiction over this action. Except as expressly admitted, Teva USA denies the allegations of this Paragraph.

66. There is a justiciable controversy between the parties hereto as to the infringement of the '298 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA admits the allegations in this paragraph.

67. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe the '298 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States.

ANSWER: Denied.

68. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of the '298 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '298 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

69. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe the '298 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes the '298 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

ANSWER: Denied.

70. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '298 patent is not enjoined.

ANSWER: Denied.

71. VIVUS does not have an adequate remedy at law.

ANSWER: Denied.

72. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count VI: Infringement of the '299 Patent

73. Plaintiff repeats and realleges the allegations of paragraphs 1-72 as though fully set forth herein.

ANSWER: Teva USA repeats and realleges its answers to the allegations of paragraphs 1-72 as though fully set forth herein.

74. Teva's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '299 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva USA admits that the submission of its ANDA vests this Court with subject matter jurisdiction over this action. Except as expressly admitted, Teva USA denies the allegations of this Paragraph.

75. There is a justiciable controversy between the parties hereto as to the infringement of the '299 patent.

ANSWER: This paragraph contains conclusions of law for which no response is

required. To the extent a response is required, Teva USA admits the allegations in this paragraph.

76. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe the '299 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States.

ANSWER: Denied.

77. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of the '299 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '299 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

78. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe the '299 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes the '299 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

ANSWER: Denied.

79. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '299 patent is not enjoined.

ANSWER: Denied.

80. VIVUS does not have an adequate remedy at law.

ANSWER: Denied.

81. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count VII: Infringement of the '057 Patent

82. Plaintiff repeats and realleges the allegations of paragraphs 1-81 as though fully set forth herein.

ANSWER: Teva USA repeats and realleges its answers to the allegations of paragraphs 1-81 as though fully set forth herein.

83. Teva's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '057 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva USA admits that the submission of its ANDA vests this Court with subject matter jurisdiction over this action. Except as expressly admitted, Teva USA denies the allegations of this Paragraph.

84. There is a justiciable controversy between the parties hereto as to the infringement of the '299 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA admits the allegations in this paragraph.

85. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe the '057 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States.

ANSWER: Denied.

86. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of the '057 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '057 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

87. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe the '057 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes the '057 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

ANSWER: Denied.

88. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '057 patent is not enjoined.

ANSWER: Denied.

89. VIVUS does not have an adequate remedy at law.

ANSWER: Denied.

90. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count VIII: Infringement of the '058 Patent

91. Plaintiff repeats and realleges the allegations of paragraphs 1-90 as though fully set forth herein.

ANSWER: Teva USA repeats and realleges its answers to the allegations of paragraphs 1-90 as though fully set forth herein.

92. Teva's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '058 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva USA admits that the submission of its ANDA vests this Court with subject matter jurisdiction over this action. Except as expressly admitted, Teva USA denies the allegations of this Paragraph.

93. There is a justiciable controversy between the parties hereto as to the infringement of the '058 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva USA admits the allegations in this paragraph.

94. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe the '058 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States.

ANSWER: Denied.

95. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of the '058 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '058 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

96. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe the '058 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes the '058 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

ANSWER: Denied.

97. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '058 patent is not enjoined.

ANSWER: Denied.

98. VIVUS does not have an adequate remedy at law.

ANSWER: Denied.

99. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

PRAYER FOR RELIEF

The remainder of VIVUS's Complaint is a prayer for relief, and does not require a response. To the extent any response is required, Teva USA denies that VIVUS is entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Teva USA hereby asserts the following defenses without undertaking or otherwise shifting any applicable burdens of proof. Teva USA reserves the right to assert additional

defenses, as warranted by facts learned through investigation and discovery.

First Affirmative Defense

The claims of the ’890, ’818, ’256, ’776, ’298, ’299, ’057, ’058 patents are invalid under one or more provision of 35 U.S.C. § 100 *et seq.*, such as sections 101, 102, 103, and/or 112, or other judicially created bases for invalidation, such as double patenting.

Second Affirmative Defense

The filing of Teva USA’s ANDA No. 208175 has not infringed and does not infringe any valid and enforceable claim, of the ‘890, ’818, ’256, ’776, ’298, ’299, ’057, ’058 patents either directly or indirectly, and either literally or under the doctrine of equivalents.

Third Affirmative Defense

The manufacture, use, sale, offer for sale, or importation of Teva USA’s ANDA Products has not infringed, does not infringe, and would not infringe any valid and enforceable claims of the ‘890, ’818, ’256, ’776, ’298, ’299, ’057, ’058 patents either directly or indirectly, and either literally or under the doctrine of equivalents.

Fourth Affirmative Defense

The complaint fails to state a claim upon which relief can be granted.

Fifth Affirmative Defense

Teva USA’s actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Teva Pharmaceuticals USA, Inc. (“Teva USA”), for its

counterclaims against Plaintiff/Counterclaim-Defendant VIVUS, Inc. ("VIVUS"), alleges as follows:

THE PARTIES

1. Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

2. Upon information and belief, VIVUS, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 351 E. Evelyn Avenue, Mountain View, California 94041.

NATURE OF THE ACTION

3. Teva USA seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that United States Patent Nos. 7,056,890 (the "'890 patent"), 7,553,818 (the "'818 patent"), 7,659,256 (the "'256 patent"), 7,674,776 (the "'776 patent"), 8,580,298 (the "'298 patent"), 8,580,299 (the "'299 patent"), 8,895,057 (the "'057 patent"), and 8,895,058 (the "'058 patent") are invalid and not infringed.

JURISDICTION AND VENUE

4. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. This Court has personal jurisdiction over VIVUS, because it subjected itself to the jurisdiction of this Court by filing its complaint here.

6. Venue is proper in this Court under 28 U.S.C. § 1391(b) and 1400(b).

7. There is an actual and justiciable controversy between the parties as to

infringement and invalidity of the ’890 patent, the ’818 patent, the ’256 patent, the ’776 patent, the ’298 patent, the ’299 patent, the ’057 patent, and the ’058 patent.

FACTUAL BACKGROUND

A. Patents-in-Suit

8. The ’890 patent, entitled “Combination therapy for effecting weight loss and treating obesity,” issued on June 6, 2006.

9. The ’818 patent, entitled “Combination therapy for effecting weight loss and treating obesity,” issued on June 30, 2009.

10. The ’256 patent, entitled “Combination therapy for effecting weight loss and treating obesity,” issued on February 9, 2010.

11. The ’776 patent, entitled “Combination therapy for effecting weight loss and treating obesity,” issued on March 9, 2010.

12. The ’298 patent, entitled “Low dose topiramate/phentermine composition and methods of use thereof,” issued on November 12, 2013.

13. The ’299 patent, entitled “Escalating dosing regimen for effecting weight loss and treating obesity,” issued on November 12, 2013.

14. The ’057 patent, entitled “Escalating dosing regimen for effecting weight loss and treating obesity,” issued on November 25, 2014.

15. The ’058 patent, entitled “Low dose topiramate/phentermine composition and methods of use thereof,” issued on November 25, 2014.

16. VIVUS is listed on the face of each of the patents as the assignee of the ’890 patent, the ’818 patent, the ’256 patent, the ’776 patent, the ’298 patent, the ’299 patent, the ’057 patent, and the ’058 patent.

B. FDA Approval Of New Brand Name Drugs

17. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

18. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

19. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using such drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

20. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

21. The FDA's duties with respect to Orange Book listings are purely ministerial. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1677 & n.2 (2012); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 243 (4th Cir. 2002). If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

C. FDA Approval of New Generic Drugs.

22. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

23. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

24. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

25. A "Paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

26. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

27. Upon receiving notice of the Paragraph IV certification, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

28. Patent holders have a significant strategic incentive to file suit within 45 days of

receiving notice of the Paragraph IV certification because doing so, regardless of merit, automatically prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

29. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, "including any substantive determination that there is no cause of action for patent infringement or invalidity," the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

D. Teva USA's ANDA

30. Teva USA submitted its ANDA No. 208175 ("Teva USA's ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of phentermine and topiramate extended-release capsules ("Teva USA's ANDA Products").

31. Upon information and belief, the FDA lists VIVUS as the holder of NDA No. 022580.

32. On information and belief, NDA No. 022580 covers VIVUS's Qsymia® (phentermine and topiramate extended-release) capsules.

33. On information and belief, VIVUS caused the '890 patent, the '818 patent, the '256 patent, the '776 patent, the '298 patent, the '299 patent, the '057 patent, and the '058 patent to be listed in the Orange Book as patents that claim the drug and/or claim a method of using such a drug for which VIVUS submitted NDA No. 022580.

34. Teva USA's ANDA includes a "Paragraph IV" certification under 21 U.S.C.

§ 505(j)(2)(A)(vii)(IV) that the ’890 patent, the ’818 patent, the ’256 patent, the ’776 patent, the ’298 patent, the ’299 patent, the ’057 patent, and the ’058 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva USA’s ANDA Products.

35. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), on March 4, 2015, Teva USA sent VIVUS notice of its Paragraph IV certification with ANDA No. 208175 (“Teva USA’s Notice Letter”).

36. Teva USA’s Notice Letter contained an offer to VIVUS of confidential access to relevant portions of Teva USA’s ANDA so that it could determine whether Teva USA’s ANDA Products would infringe any valid claim of the Orange Book-listed patents, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

37. Teva USA’s Notice Letter initiated a 45-day statutory period during which VIVUS had the opportunity to file an action for patent infringement.

38. VIVUS initiated the present litigation by filing a complaint against Teva USA and Teva Pharmaceutical Industries Ltd. on April 15, 2015. Pursuant to the Stipulation and Order of Dismissal dated June 5, 2015, the action against Teva Pharmaceutical Industries Ltd. has been dismissed. *See* ECF No. 13.

39. VIVUS has alleged in the present action that Teva USA has infringed and will infringe the ’890 patent, the ’818 patent, the ’256 patent, the ’776 patent, the ’298 patent, the ’299 patent, the ’057 patent, and the ’058 patent by filing Teva USA’s ANDA and/or by manufacturing, using, or selling Teva USA’s ANDA Products.

40. As a consequence of the foregoing, there is an actual and justiciable controversy between Teva USA and the VIVUS as to whether the claims of the ’890 patent, the ’818 patent,

the ’256 patent, the ’776 patent, the ’298 patent, the ’299 patent, the ’057 patent, and the ’058 patent are invalid and/or unenforceable, and whether those claims are being infringed or will be infringed by Teva USA’s ANDA or by the manufacture, use, sale, offer for sale, or importation of Teva USA’s ANDA Products.

COUNT I: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE ’890 PATENT

41. Teva USA incorporates by reference the allegations in paragraphs 1-40 of its counterclaims.

42. VIVUS alleges ownership of the ’890 patent and has brought claims alleging infringement of the ’890 patent.

43. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid and enforceable claim of the ’890 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Teva USA’s ANDA Products.

44. The submission of Teva USA’s ANDA No. 208175 does not infringe any valid and enforceable claim of the ’890 patent.

45. The manufacture, use, offering for sale, sale, or importation of Teva USA’s ANDA Products will not infringe, directly or indirectly, or either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’890 patent.

46. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, sale, or importation of Teva USA’s ANDA Products would infringe any valid and enforceable claim of the ’890 patent.

47. Teva USA is entitled to a judicial declaration that it has not infringed and does not

infringe any valid and enforceable claim of the ’890 patent.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE ’890 PATENT

48. Teva USA re-alleges and incorporates the allegations of paragraphs 1-47 as if fully set forth herein.

49. VIVUS alleges ownership of the ’890 patent and has brought claims alleging infringement of the ’890 patent.

50. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the ’890 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

51. One or more claims of the ’890 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting, at least for the reasons provided, including in view of the prior art references identified, in Teva USA’s Notice Letter that VIVUS received.

52. A present, genuine, and justiciable controversy exists between Teva USA and VIVUS regarding, *inter alia*, the validity of claims of the ’890 patent.

53. Teva USA is entitled to a declaration that the claims of the ’890 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

COUNT III: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE ’818 PATENT

54. Teva USA incorporates by reference the allegations in paragraphs 1-53 of its counterclaims.

55. VIVUS alleges ownership of the ’818 patent and has brought claims alleging infringement of the ’818 patent.

56. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid and enforceable claim of the ’818 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Teva USA’s ANDA Products.

57. The submission of Teva USA’s ANDA No. 208175 does not infringe any valid and enforceable claim of the ’818 patent.

58. The manufacture, use, offering for sale, sale, or importation of Teva USA’s ANDA Products will not infringe, directly or indirectly, or either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’818 patent.

59. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, sale, or importation of Teva USA’s ANDA Products would infringe any valid and enforceable claim of the ’818 patent.

60. Teva USA is entitled to a judicial declaration that it has not infringed and does not infringe any valid and enforceable claim of the ’818 patent.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF THE ’818 PATENT

61. Teva USA re-alleges and incorporates the allegations of paragraphs 1-60 as if fully set forth herein.

62. VIVUS alleges ownership of the ’818 patent and has brought claims alleging infringement of the ’818 patent.

63. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the ’818 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

64. One or more claims of the ’818 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting, at least for the reasons provided, including in view of the prior art references identified, in Teva USA’s Notice Letter that VIVUS received.

65. A present, genuine, and justiciable controversy exists between Teva USA and VIVUS regarding, inter alia, the validity of claims of the ’818 patent.

66. Teva USA is entitled to a declaration that the claims of the ’818 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

COUNT V: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE ’256 PATENT

67. Teva USA incorporates by reference the allegations in paragraphs 1-66 of its counterclaims.

68. VIVUS alleges ownership of the ’256 patent and has brought claims alleging

infringement of the ’256 patent.

69. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid and enforceable claim of the ’256 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Teva USA’s ANDA Products.

70. The submission of Teva USA’s ANDA No. 208175 does not infringe any valid and enforceable claim of the ’256 patent.

71. The manufacture, use, offering for sale, sale, or importation of Teva USA’s ANDA Products will not infringe, directly or indirectly, or either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’256 patent.

72. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, sale, or importation of Teva USA’s ANDA Products would infringe any valid and enforceable claim of the ’256 patent.

73. Teva USA is entitled to a judicial declaration that it has not infringed and does not infringe any valid and enforceable claim of the ’256 patent.

COUNT VI: DECLARATORY JUDGMENT OF INVALIDITY OF THE ’256 PATENT

74. Teva USA re-alleges and incorporates the allegations of paragraphs 1-73 as if fully set forth herein.

75. VIVUS alleges ownership of the ’256 patent and has brought claims alleging infringement of the ’256 patent.

76. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a

declaration that the claims of the ’256 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

77. One or more claims of the ’256 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting, at least for the reasons provided, including in view of the prior art references identified, in Teva USA’s Notice Letter that VIVUS received.

78. A present, genuine, and justiciable controversy exists between Teva USA and VIVUS regarding, inter alia, the validity of claims of the ’256 patent.

79. Teva USA is entitled to a declaration that the claims of the ’256 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

COUNT VII: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE ’776 PATENT

80. Teva USA incorporates by reference the allegations in paragraphs 1-79 of its counterclaims.

81. VIVUS alleges ownership of the ’776 patent and has brought claims alleging infringement of the ’776 patent.

82. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid and enforceable claim of the ’776 patent will be infringed by the

manufacture, use, sale, offer for sale, or importation into the United States of Teva USA's ANDA Products.

83. The submission of Teva USA's ANDA No. 208175 does not infringe any valid and enforceable claim of the '776 patent.

84. The manufacture, use, offering for sale, sale, or importation of Teva USA's ANDA Products will not infringe, directly or indirectly, or either literally or under the doctrine of equivalents, any valid and enforceable claim of the '776 patent.

85. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, sale, or importation of Teva USA's ANDA Products would infringe any valid and enforceable claim of the '776 patent.

86. Teva USA is entitled to a judicial declaration that it has not infringed and does not infringe any valid and enforceable claim of the '776 patent.

COUNT VIII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '776 PATENT

87. Teva USA re-alleges and incorporates the allegations of paragraphs 1-86 as if fully set forth herein.

88. VIVUS alleges ownership of the '776 patent and has brought claims alleging infringement of the '776 patent.

89. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '776 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

90. One or more claims of the ’776 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting, at least for the reasons provided, including in view of the prior art references identified, in Teva USA’s Notice Letter that VIVUS received.

91. A present, genuine, and justiciable controversy exists between Teva USA and VIVUS regarding, inter alia, the validity of claims of the ’776 patent.

92. Teva USA is entitled to a declaration that the claims of the ’776 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

COUNT IX: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE ’298 PATENT

93. Teva USA incorporates by reference the allegations in paragraphs 1-92 of its counterclaims.

94. VIVUS alleges ownership of the ’298 patent and has brought claims alleging infringement of the ’298 patent.

95. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid and enforceable claim of the ’298 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Teva USA’s ANDA Products.

96. The submission of Teva USA’s ANDA No. 208175 does not infringe any valid and enforceable claim of the ’298 patent.

97. The manufacture, use, offering for sale, sale, or importation of Teva USA's ANDA Products will not infringe, directly or indirectly, or either literally or under the doctrine of equivalents, any valid and enforceable claim of the '298 patent.

98. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, sale, or importation of Teva USA's ANDA Products would infringe any valid and enforceable claim of the '298 patent.

99. Teva USA is entitled to a judicial declaration that it has not infringed and does not infringe any valid and enforceable claim of the '298 patent.

COUNT X: DECLARATORY JUDGMENT OF INVALIDITY OF THE '298 PATENT

100. Teva USA re-alleges and incorporates the allegations of paragraphs 1-99 as if fully set forth herein.

101. VIVUS alleges ownership of the '298 patent and has brought claims alleging infringement of the '298 patent.

102. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '298 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

103. One or more claims of the '298 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting, at least for the reasons provided, including in view of

the prior art references identified, in Teva USA's Notice Letter that VIVUS received.

104. A present, genuine, and justiciable controversy exists between Teva USA and VIVUS regarding, inter alia, the validity of claims of the '298 patent.

105. Teva USA is entitled to a declaration that the claims of the '298 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

COUNT XI: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '299 PATENT

106. Teva USA incorporates by reference the allegations in paragraphs 1-105 of its counterclaims.

107. VIVUS alleges ownership of the '299 patent and has brought claims alleging infringement of the '299 patent.

108. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid and enforceable claim of the '299 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Teva USA's ANDA Products.

109. The submission of Teva USA's ANDA No. 208175 does not infringe any valid and enforceable claim of the '299 patent.

110. The manufacture, use, offering for sale, sale, or importation of Teva USA's ANDA Products will not infringe, directly or indirectly, or either literally or under the doctrine of equivalents, any valid and enforceable claim of the '299 patent.

111. There is an actual and justiciable controversy between the parties concerning

whether the manufacture, use, offering for sale, sale, or importation of Teva USA's ANDA Products would infringe any valid and enforceable claim of the '299 patent.

112. Teva USA is entitled to a judicial declaration that it has not infringed and does not infringe any valid and enforceable claim of the '299 patent.

COUNT XII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '299 PATENT

113. Teva USA re-alleges and incorporates the allegations of paragraphs 1-112 as if fully set forth herein.

114. VIVUS alleges ownership of the '299 patent and has brought claims alleging infringement of the '299 patent.

115. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '299 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

116. One or more claims of the '299 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting, at least for the reasons provided, including in view of the prior art references identified, in Teva USA's Notice Letter that VIVUS received.

117. A present, genuine, and justiciable controversy exists between Teva USA and VIVUS regarding, inter alia, the validity of claims of the '299 patent.

118. Teva USA is entitled to a declaration that the claims of the '299 patent are invalid

for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

COUNT XIII: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '057 PATENT

119. Teva USA incorporates by reference the allegations in paragraphs 1-118 of its counterclaims.

120. VIVUS alleges ownership of the '057 patent and has brought claims alleging infringement of the '057 patent.

121. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid and enforceable claim of the '057 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Teva USA's ANDA Products.

122. The submission of Teva USA's ANDA No. 208175 does not infringe any valid and enforceable claim of the '057 patent.

123. The manufacture, use, offering for sale, sale, or importation of Teva USA's ANDA Products will not infringe, directly or indirectly, or either literally or under the doctrine of equivalents, any valid and enforceable claim of the '057 patent.

124. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, sale, or importation of Teva USA's ANDA Products would infringe any valid and enforceable claim of the '057 patent.

125. Teva USA is entitled to a judicial declaration that it has not infringed and does not infringe any valid and enforceable claim of the '057 patent.

COUNT XIV: DECLARATORY JUDGMENT OF INVALIDITY OF THE '057 PATENT

126. Teva USA re-alleges and incorporates the allegations of paragraphs 1-125 as if fully set forth herein.

127. VIVUS alleges ownership of the '057 patent and has brought claims alleging infringement of the '057 patent.

128. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '057 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

129. One or more claims of the '057 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting, at least for the reasons provided, including in view of the prior art references identified, in Teva USA's Notice Letter that VIVUS received.

130. A present, genuine, and justiciable controversy exists between Teva USA and VIVUS regarding, inter alia, the validity of claims of the '057 patent.

131. Teva USA is entitled to a declaration that the claims of the '057 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

COUNT XV: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '058 PATENT

132. Teva USA incorporates by reference the allegations in paragraphs 1-131 of its counterclaims.

133. VIVUS alleges ownership of the '058 patent and has brought claims alleging infringement of the '058 patent.

134. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid and enforceable claim of the '058 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Teva USA's ANDA Products.

135. The submission of Teva USA's ANDA No. 208175 does not infringe any valid and enforceable claim of the '058 patent.

136. The manufacture, use, offering for sale, sale, or importation of Teva USA's ANDA Products will not infringe, directly or indirectly, or either literally or under the doctrine of equivalents, any valid and enforceable claim of the '058 patent.

137. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, sale, or importation of Teva USA's ANDA Products would infringe any valid and enforceable claim of the '058 patent.

138. Teva USA is entitled to a judicial declaration that it has not infringed and does not infringe any valid and enforceable claim of the '058 patent.

COUNT XVI: DECLARATORY JUDGMENT OF INVALIDITY OF THE '058 PATENT

139. Teva USA re-alleges and incorporates the allegations of paragraphs 1-138 as if fully set forth herein.

140. VIVUS alleges ownership of the ’058 patent and has brought claims alleging infringement of the ’058 patent.

141. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the ’058 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

142. One or more claims of the ’058 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability, such as double patenting, at least for the reasons provided, including in view of the prior art references identified, in Teva USA’s Notice Letter that VIVUS received.

143. A present, genuine, and justiciable controversy exists between Teva USA and VIVUS regarding, inter alia, the validity of claims of the ’058 patent.

144. Teva USA is entitled to a declaration that the claims of the ’058 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or, or other judicially-created bases for invalidation and unenforceability, such as double patenting.

TEVA USA’S PRAYER FOR RELIEF

WHEREFORE, Teva USA respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiff VIVUS as follows:

(a) declaring that Teva USA has not infringed and will not infringe any valid and

enforceable claim of U.S. Patent No. 7,056,890;

(b) declaring that the claims of U.S. Patent No. 7,056,890 are invalid;

(c) declaring that Teva USA has not infringed and will not infringe any valid and enforceable claim of U.S. Patent No. 7,553,818;

(d) declaring that the claims of U.S. Patent No. 7,553,818 are invalid;

(e) declaring that Teva USA has not infringed and will not infringe any valid and enforceable claim of U.S. Patent No. 7,659,256;

(f) declaring that the claims of U.S. Patent No. 7,659,256 are invalid;

(g) declaring that Teva USA has not infringed and will not infringe any valid and enforceable claim of U.S. Patent No. 7,674,776;

(h) declaring that the claims of U.S. Patent No. 7,674,776 are invalid;

(i) declaring that Teva USA has not infringed and will not infringe any valid and enforceable claim of U.S. Patent No. 8,580,298;

(j) declaring that the claims of U.S. Patent No. 8,580,298 are invalid;

(k) declaring that Teva USA has not infringed and will not infringe any valid and enforceable claim of U.S. Patent No. 8,580,299;

(l) declaring that the claims of U.S. Patent No. 8,580,299 are invalid;

(m) declaring that Teva USA has not infringed and will not infringe any valid and enforceable claim of U.S. Patent No. 8,895,057;

(n) declaring that the claims of U.S. Patent No. 8,895,057 are invalid;

(o) declaring that Teva USA has not infringed and will not infringe any valid and enforceable claim of U.S. Patent No. 8,895,058;

(p) declaring that the claims of U.S. Patent No. 8,895,058 are invalid;

(q) awarding Teva USA its costs and expenses in this action;

(r) if the facts demonstrate that this case is exceptional within the meaning of 35 U.S.C. § 285, awarding Teva USA its attorneys' fees, costs, and expenses in this action; and

(s) awarding such other and further relief as this Court deems just and proper.

Dated: June 18, 2015

LITE DEPALMA GREENBERG, LLC

/s/ Michael E. Patunas

Michael E. Patunas
Mayra V. Tarantino
570 Broad Street, Suite 1201
Newark, NJ 07102
Telephone: (973) 623-3000
Facsimile: (973) 623-0858
mpatunas@litedepalma.com
mtarantino@litedepalma.com

OF COUNSEL
WINSTON & STRAWN LLP
George C. Lombardi
Ivan M. Poullaos
Dan H. Hoang
35 West Wacker Drive
Chicago, Illinois 60601
Telephone: (312) 558-5600
Facsimile: (312) 558-5700
glombardi@winston.com
ipoullaos@winston.com
dhoang@winston.com

Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the following civil actions:

- *VIVUS, Inc. v. Actavis Laboratories FL, Inc.*, Civil Action No. 14-3786-SRC-CLW (D.N.J.); and
- *VIVUS, Inc. v. Actavis Laboratories FL, Inc.*, Civil Action No. 15-1636-SRC-CLW (D.N.J.).

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: June 18, 2015

LITE DEPALMA GREENBERG, LLC

/s/ Michael E. Patunas

Michael E. Patunas
Mayra V. Tarantino
570 Broad Street, Suite 1201
Newark, NJ 07102
Telephone: (973) 623-3000
Facsimile: (973) 623-0858
mpatunas@litedepalma.com
mtarantino@litedepalma.com

OF COUNSEL
WINSTON & STRAWN LLP
George C. Lombardi
Ivan M. Poullaos
Dan H. Hoang
35 West Wacker Drive
Chicago, Illinois 60601
Telephone (312) 558-5600
Facsimile (312) 558-5700
glombardi@winston.com
ipoullaos@winston.com
dhoang@winston.com

Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.

CERTIFICATE OF SERVICE

I, Michael E. Patunas, hereby certify that on this day, a true and correct copy of the foregoing DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS was served on counsel for plaintiffs via the Court's ECF system.

Dated: June 18, 2015

/s/ Michael E. Patunas
Michael E. Patunas